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SOURCE: 38 FR 27012, Sept. 27, 1973, unless otherwise noted.

§ 1500.1 Scope of subchapter.

Set forth in this subchapter C are the regulations of the Consumer Product Safety Commission issued pursuant to and for the implementation of the Federal Hazardous Substances Act as amended (see §1500.3(a)(1)).

§ 1500.2 Authority.

Authority under the Federal Hazardous Substances Act is vested in the Consumer Product Safety Commission by section 30(a) of the Consumer Product Safety Act (15 U.S.C. 2079(a)).

§ 1500.3 Definitions.

(a) *Certain terms used in this part.* As used in this part:

(1) *Act* means the Federal Hazardous Substances Act (Pub. L. 86-613, 74 Stat. 372-81 (15 U.S.C. 1261-74)) as amended by:

(i) The Child Protection Act of 1966 (Pub. L. 89-756, 80 Stat. 1303-05).

(ii) The Child Protection and Toy Safety Act of 1969 (Pub. L. 91-113, 83 Stat. 187-90).

(iii) The Poison Prevention Packaging Act of 1970 (Pub. L. 91-601, 84 Stat. 1670-74).

(2) *Commission* means the Consumer Product Safety Commission estab-

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lished May 14, 1973, pursuant to provisions of the Consumer Product Safety Act (Pub. L. 92-573, 86 Stat. 1207-33 (15 U.S.C. 2051-81)).

(b) *Statutory definitions.* Except for the definitions given in section 2 (c) and (d) of the act, which are obsolete, the definitions set forth in section 2 of the act are applicable to this part and are repeated for convenience as follows (some of these statutory definitions are interpreted, supplemented, or provided with alternatives in paragraph (c) of this section):

(1) *Territory* means any territory or possession of the United States, including the District of Columbia and the Commonwealth of Puerto Rico but excluding the Canal Zone.

(2) *Interstate commerce* means (i) commerce between any State or territory and any place outside thereof and (ii) commerce within the District of Columbia or within any territory not organized with a legislative body.

(3) *Person* includes an individual, partnership, corporation, and association.

(4)(i) *Hazardous substance* means:

(A) Any substance or mixture of substances which is toxic, corrosive, an irritant, a strong sensitizer, flammable or combustible, or generates pressure through decomposition, heat, or other means, if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.

(B) Any substance which the Commission by regulation finds, pursuant to the provisions of section 3(a) of the act, meet the requirements of section 2(f)(1)(A) of the act (restated in (A) above).

(C) Any radioactive substance if, with respect to such substance as used in a particular class of article or as packaged, the Commission determines by regulation that the substance is sufficiently hazardous to require labeling in accordance with the act in order to protect the public health.

(D) Any toy or other article intended for use by children which the Commission by regulation determines, in accordance with section 3(e) of the act,

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presents an electrical, mechanical, or thermal hazard.

(ii) *Hazardous substance* shall not apply to pesticides subject to the Federal Insecticide, Fungicide, and Rodenticide Act, to foods, drugs, and cosmetics subject to the Federal Food, Drug, and Cosmetic Act, nor to substances intended for use as fuels when stored in containers and used in the heating, cooking, or refrigeration system of a house. "Hazardous substance" shall apply, however, to any article which is not itself a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act but which is a hazardous substance within the meaning of section 2(f)(1) of the Federal Hazardous Substances Act (re-stated in paragraph (b)(4)(i) of this section) by reason of bearing or containing such a pesticide.

(iii) *Hazardous substance* shall not include any source material, special nuclear material, or byproduct material as defined in the Atomic Energy Act of 1954, as amended, and regulations issued pursuant thereto by the Atomic Energy Commission.

(5) *Toxic* shall apply to any substance (other than a radioactive substance) which has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface.

(6)(i) *Highly toxic* means any substance which falls within any of the following categories:

(A) Produces death within 14 days in half or more than half of a group of 10 or more laboratory white rats each weighing between 200 and 300 grams, at a single dose of 50 milligrams or less per kilogram of body weight, when orally administered; or

(B) Produces death within 14 days in half or more than half of a group of 10 or more laboratory white rats each weighing between 200 and 300 grams, when inhaled continuously for a period of 1 hour or less at an atmospheric concentration of 200 parts per million by volume or less of gas or vapor or 2 milligrams per liter by volume or less of mist or dust, provided such concentration is likely to be encountered by man when the substance is used in any reasonably foreseeable manner; or

(C) Produces death within 14 days in half or more than half of a group of 10 or more rabbits tested in a dosage of 200 milligrams or less per kilogram of body weight, when administered by continuous contact with the bare skin for 24 hours or less.

(ii) If the Commission finds that available data on human experience with any substance indicate results different from those obtained on animals in the dosages and concentrations specified in paragraph (b)(6)(i) of this section, the human data shall take precedence.

(7) *Corrosive* means any substance which in contact with living tissue will cause destruction of tissue by chemical action, but shall not refer to action on inanimate surfaces.

(8) *Irritant* means any substance not corrosive within the meaning of section 2(i) of the act (restated in paragraph (b)(7) of this section) which on immediate, prolonged, or repeated contact with normal living tissue will induce a local inflammatory reaction.

(9) *Strong sensitizer* means a substance which will cause on normal living tissue through an allergic or photodynamic process a hypersensitivity which becomes evident on reapplication of the same substance and which is designated as such by the Commission. Before designating any substance as a strong sensitizer, the Commission, upon consideration of the frequency of occurrence and severity of the reaction, shall find that the substance has a significant potential for causing hypersensitivity.

(10) The terms *extremely flammable*, *flammable*, and *combustible* as they apply to any substances, liquid, solid, or the contents of any self-pressurized container, are defined by regulations issued by the Commission and published at §1500.3(c)(6).

(11) *Radioactive substance* means a substance which emits ionizing radiation.

(12) *Label* means a display of written, printed, or graphic matter upon the immediate container of any substance or, in the cases of an article which is unpackaged or is not packaged in an

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immediate container intended or suitable for delivery to the ultimate consumer, a display of such matter directly upon the article involved or upon a tag or other suitable material affixed thereto. A requirement made by or under authority of the act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears (i) on the outside container or wrapper, if any there be, unless it is easily legible through the outside container or wrapper and (ii) on all accompanying literature where there are directions for use, written or otherwise.

(13) *Immediate container* does not include package liners.

(14) *Misbranded hazardous substance* means a hazardous substance (including a toy, or other article intended for use by children, which is a hazardous substance, or which bears or contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted) intended, or packaged in a form suitable, for use in the household or by children, if the packaging or labeling of such substance is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970 or if such substance, except as otherwise provided by or pursuant to section 3 of the act (Federal Hazardous Substances Act), fails to bear a label:

(i) Which states conspicuously:

(A) The name and place of business of the manufacturer, packer, distributor, or seller;

(B) The common or usual name or the chemical name (if there be no common or usual name) of the hazardous substance or of each component which contributes substantially to its hazard, unless the Commission by regulation permits or requires the use of a recognized generic name;

(C) The signal word “DANGER” on substances which are extremely flammable, corrosive, or highly toxic;

(D) The signal word “WARNING” or “CAUTION” on all other hazardous substances;

(E) An affirmative statement of the principal hazard or hazards, such as

“Flammable,” “Combustible,” “Vapor Harmful,” “Causes Burns,” “Absorbed Through Skin,” or similar wording descriptive of the hazard;

(F) Precautionary measures describing the action to be followed or avoided, except when modified by regulation of the Commission pursuant to section 3 of the act;

(G) Instruction, when necessary or appropriate, for first-aid treatment;

(H) The word *Poison* for any hazardous substance which is defined as “highly toxic” by section 2(h) of the act (restated in paragraph (b)(6) of this section);

(I) Instructions for handling and storage of packages which require special care in handling or storage; and

(J) The statement (1) “Keep out of the reach of children” or its practical equivalent, or, (2) if the article is intended for use by children and is not a banned hazardous substance, adequate directions for the protection of children from the hazard; and

(ii) On which any statements required under section 2(p)(1) of the act (restated in paragraph (b)(14)(i) of this section) are located prominently and are in the English language in conspicuous and legible type in contrast by typography, layout, or color with other printed matter on the label.

Misbranded hazardous substance also means a household substance as defined in section 2(2)(D) of the Poison Prevention Packaging Act of 1970 if it is a substance described in section 2(f)(1) of the Federal Hazardous Substances Act (restated in paragraph (b)(4)(i)(A) of this section) and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970.

(15)(i) *Banned hazardous substance* means:

(A) Any toy, or other article intended for use by children, which is a hazardous substance, or which bears or contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted; or

(B) Any hazardous substance intended, or packaged in a form suitable, for use in the household, which the Commission by regulation classifies as

a “banned hazardous substance” on the basis of a finding that, notwithstanding such cautionary labeling as is or may be required under the act for that substance, the degree or nature of the hazard involved in the presence or use of such substance in households is such that the objective of the protection of the public health and safety can be adequately served only by keeping such substance, when so intended or packaged, out of the channels of interstate commerce; *Provided*, That the Commission by regulation (1) shall exempt from section 2(q)(1)(A) of the act (restated in paragraph (b)(15)(i)(A) of this section) articles, such as chemistry sets, which by reason of their functional purpose require the inclusion of the hazardous substance involved, or necessarily present an electrical, mechanical, or thermal hazard, and which bear labeling giving adequate directions and warnings for safe use and are intended for use by children who have attained sufficient maturity, and may reasonably be expected, to read and heed such directions and warnings, and (2) shall exempt from section 2(q)(1)(A) of the act (restated in paragraph (b)(15)(i)(A) of this section), and provide for the labeling of, common fireworks (including toy paper caps, cone fountains, cylinder fountains, whistles without report, and sparklers) to the extent that the Commission determines that such articles can be adequately labeled to protect the purchasers and users thereof.

(ii) Proceedings for the issuance, amendment, or repeal of regulations pursuant to section 2(q)(1)(B) of the act (restated in paragraph (b)(15)(i)(B) of this section) shall be governed by the provisions of section 701 (e), (f), and (g) of the Federal Food, Drug, and Cosmetic Act: *Provided*, That if the Commission finds that the distribution for household use of the hazardous substance involved presents an imminent hazard to the public health, the Commission may by order published in the FEDERAL REGISTER give notice of such finding, and thereupon such substance when intended or offered for household use, or when so packaged as to be suitable for such use, shall be deemed to be a “banned hazardous substance” pending

the completion of proceedings relating to the issuance of such regulations.

(16) “Electrical hazard”—an article may be determined to present an electrical hazard if, in normal use or when subjected to reasonably foreseeable damage or abuse, its design or manufacture may cause personal injury or illness by electric shock.

(17) “Mechanical hazard”—an article may be determined to present a mechanical hazard if, in normal use or when subjected to reasonably foreseeable damage or abuse, its design or manufacture presents an unreasonable risk of personal injury or illness:

(i) From fracture, fragmentation, or disassembly of the article;

(ii) From propulsion of the article (or any part or accessory thereof);

(iii) From points or other protrusions, surfaces, edges, openings, or closures;

(iv) From moving parts;

(v) From lack or insufficiency of controls to reduce or stop motion;

(vi) As a result of self-adhering characteristics of the article;

(vii) Because the article (or any part or accessory thereof) may be aspirated or ingested;

(viii) Because of instability; or

(ix) Because of any other aspect of the article’s design or manufacture.

(18) “Thermal hazard”—an article may be determined to present a thermal hazard if, in normal use or when subjected to reasonably foreseeable damage or abuse, its design or manufacture presents an unreasonable risk of personal injury or illness because of heat as from heated parts, substances, or surfaces.

(c) *Certain statutory definitions interpreted, supplemented, or provided with alternatives.* The following items interpret, supplement, or provide alternatives to definitions set forth in section 2 of the act (and restated in paragraph (b) of this section):

(1) To provide flexibility as to the number of animals tested, and to emphasize *in vitro* testing methods, the following is an alternative to the definition of “highly toxic” in section 2(h) of the act (and paragraph (b)(6) of this section); *Highly toxic* means:

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(i) A substance determined by the Commission to be highly toxic on the basis of human experience; and/or

(ii) A substance that produces death within 14 days in half or more than half of a group of:

(A) White rats (each weighing between 200 and 300 grams) when a single dose of 50 milligrams or less per kilogram of body weight is administered orally;

(B) White rats (each weighing between 200 and 300 grams) when a concentration of 200 parts per million by volume or less of gas or vapor, or 2 milligrams per liter by volume or less of mist or dust, is inhaled continuously for 1 hour or less, if such concentration is likely to be encountered by man when the substance is used in any reasonably foreseeable manner; and/or

(C) Rabbits (each weighing between 2.3 and 3.0 kilograms) when a dosage of 200 milligrams or less per kilogram of body weight is administered by continuous contact with the bare skin for 24 hours or less by the method described in § 1500.40.

The number of animals tested shall be sufficient to give a statistically significant result and shall be in conformity with good pharmacological practices.

(iii) A substance that produces a result of ‘highly toxic’ in any of the approved test methods described in the CPSC’s animal testing policy set forth in 16 CFR 1500.232, including data from *in vitro* or *in silico* test methods that the Commission has approved; or a validated weight-of-evidence analysis comprising all of the following that are available: existing human and animal data, structure activity relationships, physicochemical properties, and chemical reactivity data.

(2) To give specificity to the definition of “toxic” in section 2(g) of the act (and restated in paragraph (b)(5) of this section), the following supplements that definition. “Toxic” applies to any substance that is “toxic” (but not “highly toxic”) on the basis of human experience. The following categories are not intended to be inclusive.

(i) The number of animals tested shall be sufficient to give a statistically significant result and shall be in conformity with good pharma-

cological practices. *Toxic* also applies to any substance that can be labeled as such, based on the outcome of any of the approved test methods described in the CPSC’s animal testing policy set forth in 16 CFR 1500.232, including data from, including data from *in vitro* or *in silico* test methods that the Commission has approved; or a validated weight-of-evidence analysis comprising all of the following that are available: existing human and animal data, structure activity relationships, physicochemical properties, and chemical reactivity data.

(ii) *Chronic toxicity*. A substance is toxic because it presents a chronic hazard if it falls into one of the following categories. (For additional information see the chronic toxicity guidelines at 16 CFR 1500.135.)

(A) *For Carcinogens*. A substance is toxic if it is or contains a known or probable human carcinogen.

(B) *For Neurotoxicological Toxicants*. A substance is toxic if it is or contains a known or probable human neurotoxin.

(C) *For Developmental or Reproductive Toxicants*. A substance is toxic if it is or contains a known or probable human developmental or reproductive toxicant.

(3) Corrosive means a substance that causes visible destruction or irreversible alterations in the tissue at the site of contact. A test for a corrosive substance is whether, by human experience, such tissue destruction occurs at the site of application. A substance would be considered corrosive to the skin if a weight-of-evidence analysis suggests that it is corrosive, or validated *in vitro* test method suggests that it is corrosive, or if, when tested by the *in vivo* technique described in § 1500.41, the structure of the tissue at the site of contact is destroyed or changed irreversibly in 24 hours or less. Other appropriate tests should be applied when contact of the substance with other than skin tissue is being considered. A substance could also be labeled corrosive based on the outcome of any of the approved test methods described in the CPSC’s animal testing policy set forth in 16 CFR 1500.232, including data from *in vitro* or *in silico* test methods that the Commission has approved; or a validated weight-of-evidence analysis

comprising all of the following that are available: Existing human and animal data, structure activity relationships, physicochemical properties, and chemical reactivity data.

(4) The definition of irritant in section 2(j) of the act (restated in paragraph (b)(8) of this section) is supplemented by the following: *Irritant* includes primary irritant to the skin, as well as substances irritant to the eye or to mucous membranes. *Primary irritant* means a substance that is not corrosive and that human experience data indicate is a primary irritant; and/or means a substance that results in an empirical score of five or more when tested by the method described in 1500.41; and/or a substance that can be considered a primary irritant based on the outcome of any of the approved test methods described in the CPSC's animal testing policy set forth in 16 CFR 1500.232, including data from *in vitro* or *in silico* test methods that the Commission has approved; or a validated weight-of-evidence analysis comprising all of the following that are available: existing human and animal data, structure activity relationships, physicochemical properties, and chemical reactivity data. *Eye irritant* means a substance that human experience data indicate is an irritant to the eye; and/or means a substance for which a positive test is obtained when tested by the method described in 1500.42; and/or means a substance that can be considered an eye irritant based on the outcome of any of the approved test methods described in the CPSC's animal testing policy set forth in 16 CFR 1500.232, including data from *in vitro* or *in silico* test methods that the Commission has approved; or a validated weight-of-evidence analysis comprising all of the following that are available: existing human and animal data, structure activity relationships, physicochemical properties, and chemical reactivity data.

(5) The definition of *strong sensitizer* in section 2(k) of the Federal Hazardous Substances Act (restated in paragraph (b)(9) of this section) is supplemented by the following definitions:

(i) *Sensitizer*. A sensitizer is a substance that is capable of inducing a state of immunologically mediated

hypersensitivity (including allergic photosensitivity) following a variable period of exposure to that substance. Hypersensitivity to a substance will become evident by an allergic reaction elicited upon reexposure to the same substance.

(ii) *Significant potential for causing hypersensitivity*. (A) Before designating any substance a "strong sensitizer," the Commission shall find that the substance has significant potential for causing hypersensitivity. *Significant potential for causing hypersensitivity* is a relative determination that must be made separately for each substance. The determination may be based on documented medical evidence of hypersensitivity reactions upon subsequent exposure to the same substance obtained from epidemiological surveys or case histories; controlled *in vivo* or *in vitro* experimental studies; susceptibility profiles (*e.g.*, genetics, age, gender, atopic status) in non-sensitized or allergic subjects; and chemical or functional properties of the substance.

(B) In determining whether a substance is a "strong" sensitizer, the Commission shall consider the available data for a number of factors, following a weight-of-evidence approach. The following factors (if available), ranked in descending order of importance, should be considered: well-conducted clinical and diagnostic studies, epidemiological studies, with a preference for general population studies over occupational studies, well-conducted animal studies, well-conducted *in vitro* test studies, cross-reactivity data, and case histories.

(C) Additional consideration may be given to Quantitative Structure-Activity Relationships (QSARs), *in silico* data, specific human sensitization threshold values, other data on potency and sensitizer bioavailability, if data are available and the methods validated. Bioavailability is the dose of the allergen available to interact with a tissue. Bioavailability is a reflection of how well the skin or another organ can absorb the allergen and the actual penetrating ability of the allergen, including factors such as size and composition of the chemical.

(D) Criteria for a “well-conducted” study would include: validated outcomes, relevant dosing, route of administration, and use of appropriate controls. Studies should be carried out according to national and/or international test guidelines and according to good laboratory practice (GLP), compliance with good clinical practice (GCP), and good epidemiological practice (GEP).

(E) Before the Commission designates any substance as a “strong” sensitizer, frequency of occurrence and range of severity of reactions in exposed subpopulations having average or high susceptibility will be considered. The minimal severity of a reaction for the purpose of designating a material as a “strong sensitizer” is a clinically important reaction. A clinically important reaction would be considered one with a significant impact on quality of life. Consideration should be given to the location of the hypersensitivity response, such as the face, hands, and feet as well as persistence of clinical manifestations. For example, strong sensitizers may produce substantial illness, including any or all of the following: substantial physiological effects, such as discomfort and distress, substantial hardship, functional or structural impairment, persistent morbidity, or in rare cases, mortality.

(iii) *Normal living tissue.* The allergic hypersensitivity reaction occurs in normal living tissues, including the skin, mucous membranes (*e.g.*, ocular, oral), and other organ systems, such as the respiratory tract and gastrointestinal tract, either singularly or in combination, following sensitization by contact, ingestion, or inhalation.

(6) The Consumer Product Safety Commission, by the regulations published in this section, defines the terms *extremely flammable*, *flammable*, and *combustible*, appearing in section 2(1) of the Federal Hazardous Substances Act, as follows:

(i) The term *extremely flammable* shall apply to any substance which has a flashpoint at or below 20 °F (–6.7 °C) as determined by the test method described at §1500.43a, except that, any mixture having one component or more with a flashpoint higher than 20 °F (–6.7 °C) which comprises at least 99

percent of the total volume of the mixture is not considered to be an extremely flammable substance.

(ii) The term *flammable* shall apply to any substance having a flashpoint above 20 °F (–6.7 °C) and below 100 °F (37.8 °C), as determined by the method described at §1500.43a, except that:

(A) Any mixture having one component or more with a flashpoint at or above 100 °F (37.8 °C) which comprises at least 99 percent of the total volume of the mixture is not considered to be a flammable substance; and

(B) Any mixture containing 24 percent or less of water miscible alcohols, by volume, in aqueous solution is not considered to be flammable if the mixture does not present a significant flammability hazard when used by consumers.

(iii) The term *combustible* shall apply to any substance having a flashpoint at or above 100 °F (37.8 °C) to and including 150 °F (65.6 °C) as determined by the test method described at §1500.43a, except that:

(A) Any mixture having one component or more with a flashpoint higher than 150 °F (65.6 °C) which comprises at least 99 percent of the total volume of the mixture is not considered to be a combustible hazardous substance; and

(B) Any mixture containing 24 percent or less of water miscible alcohols, by volume, in aqueous solution is not considered to be combustible if the mixture does not present a significant flammability hazard when used by consumers.

(iv) To determine flashpoint temperatures for purposes of enforcing and administering requirements of the Federal Hazardous Substances Act applicable to “extremely flammable,” “flammable,” and “combustible” hazardous substances, the Commission will follow the procedures set forth in §1500.43a. However, the Commission will allow manufacturers and labelers of substances and products subject to those requirements to rely on properly conducted tests using the Tagliabue open-cup method which was in effect prior to the issuance of §1500.43a (as published at 38 FR 27012, September 27, 1973, and set forth below), and the definitions of the terms “extremely flammable,” “flammable,” and “combustible” in

this section before its amendment (as published at 38 FR 27012, September 27, 1983, and amended 38 FR 30105, November 1, 1973, set forth in the note following this section) if all of the following conditions are met:

(A) The substance or product was subject to and complied with the requirements of the Federal Hazardous Substances Act for “extremely flammable,” “flammable,” or “combustible” hazardous substances before the effective date of §1500.43a; and

(B) No change has been made to the formulation or labeling of such substance or product after the effective date of §1500.43a, prescribing a closed-cup test apparatus and procedure.

(v) *Extremely flammable solid* means a solid substance that ignites and burns at an ambient temperature of 80 °F or less when subjected to friction, percussion, or electrical spark.

(vi) *Flammable solid* means a solid substance that, when tested by the method described in §1500.44, ignites and burns with a self-sustained flame at a rate greater than one-tenth of an inch per second along its major axis.

(vii) *Extremely flammable contents of self-pressurized container* means contents of a self-pressurized container that, when tested by the method described in §1500.45, a flashback (a flame extending back to the dispenser) is obtained at any degree of valve opening and the flashpoint, when tested by the method described in §1500.43a is less than 20 °F (−6.7 °C).

(viii) *Flammable contents of self-pressurized container* means contents of a self-pressurized container that, when tested by the method described in §1500.45, a flame projection exceeding 18 inches is obtained at full valve opening, or flashback (a flame extending back to the dispenser) is obtained at any degree of valve opening.

(7) The definition of *hazardous substance* in section 2(f)(1)(A) of the act (restated in paragraph (b)(4)(i)(A) of this section) is supplemented by the following definitions or interpretations or terms used therein:

(i) A substance or mixture of substances that “generates pressure through decomposition, heat, or other means” is a hazardous substance:

(A) If it explodes when subjected to an electrical spark, percussion, or the flame of a burning paraffin candle for 5 seconds or less.

(B) If it expels the closure of its container, or bursts its container, when held at or below 130 °F. for 2 days or less.

(C) If it erupts from its opened container at a temperature of 130 °F. or less after having been held in the closed container at 130 °F. for 2 days.

(D) If it comprises the contents of a self-pressurized container.

(ii) *Substantial personal injury or illness* means any injury or illness of a significant nature. It need not be severe or serious. What is excluded by the word “substantial” is a wholly insignificant or negligible injury or illness.

(iii) *Proximate result* means a result that follows in the course of events without an unforeseeable, intervening, independent cause.

(iv) *Reasonably foreseeable handling or use* includes the reasonably foreseeable accidental handling or use, not only by the purchaser or intended user of the product, but by all others in a household, especially children.

(8) The definition of “radioactive substance” in section 2(m) of the act (restated in paragraph (b)(11) of this section) is supplemented by the following: *Radioactive substance* means a substance which, because of nuclear instability, emits electromagnetic and/or particulate radiation capable of producing ions in its passage through matter. Source materials, special nuclear material, and byproduct materials described in section 2(f)(3) of the act are exempt.

(9) In the definition of “label” in section 2(n) of the act (restated in paragraph (b)(12) of this section), a provision stipulates that words, statements, or other information required to be on the label must also appear on all accompanying literature where there are directions for use, written or otherwise. To make this provision more specific, “accompanying literature” is interpreted to mean any placard, pamphlet, booklet, book, sign, or other written, printed, or graphic matter or visual device that provides directions for use, written or otherwise, and that

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is used in connection with the display, sale, demonstration, or merchandising of a hazardous substance intended for or packaged in a form suitable for use in the household or by children.

(10) The definition of “misbranded hazardous substance” in section 2(p) of this act (restated in paragraph (b)(14) of this section) is supplemented by the following definitions or interpretations of terms used therein:

(i) *Hazardous substances intended, or packaged in a form suitable, for use in the household* means any hazardous substance, whether or not packaged, that under any customary or reasonably foreseeable condition of purchase, storage, or use may be brought into or around a house, apartment, or other place where people dwell, or in or around any related building or shed including, but not limited to, a garage, carport, barn, or storage shed. The term includes articles, such as polishes or cleaners, designed primarily for professional use but which are available in retail stores, such as hobby shops, for nonprofessional use. Also included are items, such as antifreeze and radiator cleaners, that although principally for car use may be stored in or around dwelling places. The term does not include industrial supplies that might be taken into a home by a serviceman. An article labeled as, and marketed solely for, industrial use does not become subject to this act because of the possibility that an industrial worker may take a supply for his own use. Size of unit or container is not the only index of whether the article is suitable for use in or around the household; the test shall be whether under any reasonably foreseeable condition of purchase, storage, or use the article may be found in or around a dwelling.

(ii) *Conspicuously* in section 2(p)(1) of the act and *prominently* and *conspicuous* in section 2(p)(2) of the act mean that, under customary conditions of purchase, storage, and use, the required information shall be visible, noticeable, and in clear and legible English. Some factors affecting a warning’s prominence and conspicuousness are: Location, size of type, and contrast of printing against background. Also bearing on the effectiveness of a warn-

ing might be the effect of the package contents if spilled on the label.

NOTE: The definitions of *extremely flammable*, *flammable*, and *combustible* hazardous substances set forth above in paragraphs (b)(10) and (c)(6) are effective August 10, 1987. The definitions remaining in effect until August 10, 1987, as published at 38 FR 27012, Sept. 27, 1973, and amended at 38 FR 30105, Nov. 1, 1973, are set forth below. Manufacturers and labelers of products subject to the Federal Hazardous Substances Act may continue to use these definitions for labeling of those products under the conditions set forth in §1500.3(c)(6)(iv), as amended.

(b)(10) *Extremely flammable* shall apply to any substance which has a flashpoint at or below 20 °F. as determined by the Tagliabue Open Cup Tester; *flammable* shall apply to any substance which has a flashpoint of above 20 °F., to and including 80 °F., as determined by the Tagliabue Open Cup Tester; and *combustible* shall apply to any substance which has a flashpoint above 80 °F. to and including 150 °F., as determined by the Tagliabue Open Cup Tester; except that the flammability or combustibility of solids and of the contents of self-pressurized containers shall be determined by methods found by the Commission to be generally applicable to such materials or containers, respectively, and established by regulations issued by the Commission, which regulations shall also define the terms *flammable*, *combustible*, and *extremely flammable* in accord with such methods.

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(c)(6)(i) *Extremely flammable* means any substance that has a flashpoint at or below 20 °F. as determined by the method described in §1500.43.

(ii) *Flammable* means any substance that has a flashpoint of above 20 °F., to and including 80 °F., as determined by the method described in §1500.43.

[38 FR 27012, Sept. 27, 1973, as amended at 38 FR 30105, Nov. 1, 1973; 49 FR 22465, May 30, 1984; 51 FR 28536, Aug. 8, 1986; 51 FR 29096, Aug. 14, 1986; 51 FR 30209, Aug. 25, 1986; 57 FR 46669, Oct. 9, 1992; 77 FR 73293, Dec. 10, 2012; 79 FR 8831, Feb. 14, 2014]

§ 1500.4 Human experience with hazardous substances.

(a) Reliable data on human experience with any substance should be taken into account in determining whether an article is a “hazardous substance” within the meaning of the act. When such data give reliable results different from results with animal